REMARKS

Applicant respectfully requests reconsideration. Claims 2, 5, 7, 9, 14, 76-79 and 81-83 were previously pending in this application. By this amendment, Applicant is canceling claims 5, 14, 76, 78, 81 and 83 without prejudice or disclaimer. Claims 2 and 9 have been amended. New claims 88-95 have been added. As a result, claims 2, 7, 9, 77, 79, 82 and 88-95 are pending for examination with claims 2, 9 and 88 being independent claims. No new matter has been added.

Rejections Under 35 U.S.C. §112

A. The Examiner rejected claims 5, 14, 78 and 83 under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description on the basis that the limitation of 0-10 amino acids added to either or both ends of the amino acid sequence encompasses an endosomal targeting peptide that can only be 2-11 amino acids.

The Examiner suggested that Applicant add two new independent claims similar to claims 2 and 9 with the additional limitation of an endosomal targeting peptide of claim 5.

Although Applicant disagrees with the Examiner's interpretation of the claims, in that the endosomal targeting peptide is a separate peptide independent of any addition or substitution made to the claimed peptide, Applicant has canceled claims 5, 14, 78 and 83 and has added the new claims as suggested. Thus, new claim 88 corresponds to previously pending claim 5, and new claim 92 corresponds to previously pending claim 14. New claims 89-91 and 93-95 incorporate additional limitations from pending claims.

Accordingly, withdrawal of the rejection of claims 5, 14, 78 and 83 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

B. The Examiner rejected claims 5 and 14 under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description on the basis that the specification discloses human invariant chain Ii and LAMP-1 as endosomal targeting signals but the claim encompasses a vast genus of potential agents which could function as such an endosomal targeting signal.

Applicant has limited the endosomal targeting signal in newly added claims 88-95 to human invariant chain Ii or LAMP-1. Accordingly, withdrawal of the rejection of claims 5 and 14 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejections Under 35 U.S.C. § 102

A. The Examiner rejected claims 2, 9, 76, 77, 81 and 82 under 35 U.S.C. § 102 as being anticipated by Fikes et al. (PCT Publication No. WO 95/04542). Applicant respectfully traverses the rejection and requests withdrawal of the rejection.

The Examiner has based the rejection on SEQ ID NO:15 as disclosed in Fikes. The Examiner asserts that this sequence anticipates SEQ ID NO:7 of our claims because Fikes' PCT application discloses that SEQ ID NO:15 can have additional MAGE 1 residues at both ends which encompasses SEQ ID NO:7. The Examiner has stated that the claimed peptides are immediately envisaged by the teachings of Fikes. The Examiner asserts that Fikes teaches MAGE 1 peptide compositions containing a MAGE 1 class I binding peptide and a MAGE 1 class II binding peptide. Applicant disagrees with the Examiner's assertions for the following reasons.

The disclosure of Fikes is far too broad a genus of peptide-based compositions to anticipate the claimed invention. Fikes discloses that a peptide "derived from the region of SEQ ID NO:1 has at least seven amino acids wherein a majority of amino acids of the peptide will be identical or substantially homologous when compared to the amino acids comprising the corresponding portion of the naturally occurring MAGE-1 sequence" (see page 5, lines 16-22). Fikes further states that "the peptide can be optionally flanked and/or modified at one or both of the N- and C- termini, as desired by amino acids from MAGE sequences, particularly MAGE-1,

amino acids to facilitate linking, other N- and C-terminal modifications, linked to carriers, etc...." (see page 5, lines 24-28).

Fikes further discloses that the peptides "need not be identical to those exemplary peptides identified above or to a particular MAGE or MAGE-1 protein sequence, so long as the subject compounds are able to bind to the appropriate MHC molecule and provide for cytotoxic T lymphocytic or T helper activity against cells which express a MAGE antigen. Therefore, the peptides may be subject to various changes, such as insertions, deletions, and substitutions, either conservative or non-conservative...." (see page 11, lines 16-38). Fikes thus discloses that amino acids and other moieties other than those of MAGE-1 may be added to the peptide.

Therefore Fikes discloses a very large genus of compounds having as a common feature a region of SEQ ID NO:1 of at least seven amino acids. As demonstrated below, the Fikes genus of compounds is incalculably large, even if, for the sake of argument, the genus is restricted to SEQ ID NO:15 and the remaining sequences disclosed by Fikes to be part of this genus (regions of SEQ ID NO:1 of at least seven amino acids) are ignored.

As noted above, Fikes teaches that the peptide can be modified at one or both termini. The disclosed terminal modifications include the following: amino acids from MAGE sequences (of which there are at least 13 polypeptide sequences), other amino acids (e.g., to facilitate linking), other unspecified (and therefore vast in number) N- and C-terminal modifications, and unspecified (and therefore vast in number) carriers. The number of amino acids that can be added is not restricted, nor are the kinds of amino acids. There are no limitations on other N- and C-terminal modifications. There are no limitations on the types of "carriers" that can be added to the peptide. There is no prohibition against combining several of these classes of additions. Thus, even in the simplest case (SEQ ID NO:15), Fikes discloses a vast genus of compounds.

However, there is even more variability disclosed by Fikes. The core of the molecules in the genus are subject to variation from the amino acid sequence in SEQ ID NO:1, because Fikes discloses that "a majority of amino acids of the peptide will be identical or substantially

homologous when compared to the amino acids comprising the corresponding portion of the naturally occurring MAGE-1 sequence." (see page 5, lines 16-22) This introduces additional variability into the structure of the molecule, and therefore further increases the size of the genus disclosed by Fikes.

Fikes discloses still more variability in stating that the sequences of the peptides in the genus "need not be identical to those exemplary peptides identified above or to a particular MAGE or MAGE-1 protein sequence, so long as the subject compounds are able to bind to the appropriate MHC molecule and provide for cytotoxic T lymphocytic or T helper activity against cells which express a MAGE antigen." (see page 11, lines 16-38) Therefore there is essentially no limit on the composition of the genus.

A genus of such overwhelming size and complexity is not sufficient under the law to serve as an anticipation of the invention now claimed. The Examiner correctly states the state of the law as it pertains to compounds that can be "at once envisaged" from a particular formula, or as part of a particular genus. However, that statement of the law is not entirely complete.

As noted in MPEP 2131.02 as cited by the Examiner, when the inventive compound is not specifically named, but must be selected from various substituents disclosed in a reference, "anticipation can only be found if the classes of substituents are sufficiently limited or well delineated." Office Action at page 6. Applicant argues that the Fikes disclosure does not meet even this test, because one of ordinary skill in the art could not possibly "at once envisage" Applicant's claimed compounds, given the vastness of the genus disclosed by Fikes.

The size and complexity of the Fikes genus can be contrasted with the genera of compounds in the cases in which anticipation was found. For example, in In re Petering, the genus was a limited class of about 20 compounds, and the claimed compound was 1 of the 20. In In re Schaumann, the "generic formula seemed to describe an infinite number of compounds" while claim 1 included a much more limited group of compounds having only one substituent. (Cited in Office Action at page 7)

The instant facts differ from the two foregoing cases because Fikes does not teach a small, limited genus of compounds.

The Examiner points to certain statements in the Fikes references as disclosing Applicant's claimed invention. However, the fact that the Examiner includes Fikes' broader disclosure of, e.g., flanking amino acids, indicates that Applicant's claimed compounds are present, if at all, only in the broad genus disclosed by Fikes, and therefore cannot possibly be "at once envisaged" as is required under the law. Notwithstanding the Examiner's apparently hindsight-aided selection of portions of Fikes' disclosed genus, there is nothing in the Fikes reference itself that provides classes of substituents that are sufficiently limited or well delineated to provide the specificity and limited genus size that is required for anticipation. Without the benefit of hindsight, it is not possible that one of ordinary skill in the art would "at once envisage" and select Applicant's claimed compounds from the vast genus of compounds disclosed by Fikes.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 2, 7, 9, 76, 77, 79, 81 and 82 under 35 U.S.C. §103(a) as unpatentable over Fikes et al. in view of U.S. Patent No. 6,043,347 (Gelder et al.).

The Examiner asserts Gelder provides a teaching of modified peptides containing D-amino acids, which when combined with the teachings of Fikes as described above, renders the claimed invention obvious. The Examiner asserts that one of ordinary skill in the art would have combined the Fikes and Gelder references because (1) Fikes teaches the claimed peptides except for the D-amino acids, and (2) Gelder teaches D-amino acids that exhibit increased stability. Applicant respectfully disagrees and traverses the rejection.

First, as described above, Fikes teaches a vast genus that is not legally sufficient to teach the claimed peptides. Gelder does not provide the elements missing from Fikes, i.e., a specific disclosure of Applicant's claimed peptides.

Second, the Examiner does not provide an adequate motivation to combine the references to make a *prima facie* case of obviousness. The only apparent reason for the combination is that Gelder teaches that D-amino acids confer increased stability. Gelder does not, however, teach that any peptide should be modified, nor does Fikes teach any need for peptide stability. Therefore, there does not appear to be the requisite specific motivation needed to combine references effectively.

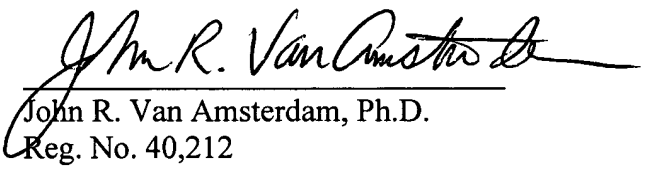
Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By: 

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